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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,301	06/11/2007	**Salehuzzaman Shah**	080426-000000US	2658

20350 7590 12/22/2010

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EXAMINER	
MCELWAIN, ELIZABETH F	
ART UNIT	**PAPER NUMBER**
1638	

MAIL DATE	DELIVERY MODE
12/22/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,301	SHAH ET AL.	
	Examiner	Art Unit	
	Elizabeth F. McElwain	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *13 October 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,26 and 32* is/are pending in the application.

4a) Of the above claim(s) *1-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-17,26 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/6/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed November 13, 2010 has been entered.

2. Claims 1-17, 26 and 32 are pending.

3. Claims 11-17, 26 and 32 are examined on the merits.

Claim Objections

4. Claim 26 is objected to for a typographical error in the recitation of "ncontaining".

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 11-15, 26 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Nishizawa et al (US Patent 6,043,411 in IDS).

7. The claims are drawn to a nucleic acid molecule encoding a delta-9 desaturase coding sequence from a prokaryote, such as SEQ ID NO: 2, operably linked to the endoplasmic reticulum (ER) retention and retrieval signal sequence of SEQ ID NO: 3 (KKXX), and said sequence in a vector, a host cell, a plant cell or transgenic plant, and a method comprising extracting oil from said plant.

8. Nishizawa et al teach a delta-9 desaturase coding sequence from the prokaryote Anacystis that encodes a polypeptide of SEQ ID NO: 2 (see sequence alignment below), wherein SEQ ID

NO: 2 comprises the amino acid sequence of SEQ ID NO: 3 (KKXX at amino acids 63-66) and transformation of plants and extraction of oils with reduced saturation of fatty acids (see the Brief Description at paragraphs 9-27, and the Detailed Description at paragraphs 47-58). In addition, Nishizawa et al teach that this prokaryotic gene is desirable to express in plants because it acts on 16:0 fatty acids that are abundant in plants (at paragraph 3 of the Brief Description), and that any known plant regulatory elements can be used in combination with said coding sequence for transformation of plant cells (see paragraph 15 of the Detailed Description).

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RESULT 1
US-08-663-082-4
; Sequence 4, Application US/08663082
; Patent No. 6043411
;  GENERAL INFORMATION:
;    APPLICANT:  NISHIZAWA, Osamu
;    APPLICANT:  TOGURI, Toshihiro
;    TITLE OF INVENTION:  GENE FOR FATTY ACID DESATURASE, VECTOR
;    TITLE OF INVENTION:  CONTAINING SAID GENE, PLANT TRANSFORMED WITH SAID GENE,
;    TITLE OF INVENTION:  AND PROCESS FOR CREATING SAID PLANT
;    CURRENT APPLICATION DATA:
;      APPLICATION NUMBER:  US/08/663,082
;      FILING DATE:  25-JUN-1996
;      CLASSIFICATION:  800
;    PRIOR APPLICATION DATA:
;      APPLICATION NUMBER:  WO PCT/JP94/02288
;      FILING DATE:  28-DEC-1994
;    PRIOR APPLICATION DATA:
;      APPLICATION NUMBER:  JP 93/352858
;      FILING DATE:  28-DEC-1993
;   INFORMATION FOR SEQ ID NO:  4:
;    SEQUENCE CHARACTERISTICS:
;      LENGTH:  278 amino acids
;      TYPE:  amino acid
;      STRANDEDNESS:
;      TOPOLOGY:  linear
;    ORIGINAL SOURCE:
;      ORGANISM:  Anacystis nidulans
;      STRAIN:  R2-SPc
US-08-663-082-4

  Query Match             100.0%;  Score 1572;  DB 2;  Length 278;
  Best Local Similarity   100.0%;
  Matches  278;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 MTLAIRPKLAFNWPTALFMVAIHIGALLAFLPANFNWPAVGVMVALYYITGCFGITLGWH 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MTLAIRPKLAFNWPTALFMVAIHIGALLAFLPANFNWPAVGVMVALYYITGCFGITLGWH 60
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Qy          61 RLISHRSFEVPKWLEYVLVFCGTLAMQHGPIEWIGLHRHHHLHSDQDVDHHDSNKGFLWS 120
               ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          61 RLISHRSFEVPKWLEYVLVFCGTLAMQHGPIEWIGLHRHHHLHSDQDVDHHDSNKGFLWS 120

Qy         121 HFLWMIYEIPARTEVDKFTRDIAGDPVYRFFNKYFFGVQVLLGVLLYAWGEAWVGNGWSF 180
               ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         121 HFLWMIYEIPARTEVDKFTRDIAGDPVYRFFNKYFFGVQVLLGVLLYAWGEAWVGNGWSF 180

Qy         181 VVWGIFARLVVVYHVTWLVNSATHKFGYRSHESGDQSTNCWWVALLAFGEGWHNNHHAYQ 240
               ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         181 VVWGIFARLVVVYHVTWLVNSATHKFGYRSHESGDQSTNCWWVALLAFGEGWHNNHHAYQ 240

Qy         241 YSARHGLQWWEFDLTWLIICGLKKVGLARKIKVASPNN 278
               ||||||||||||||||||||||||||||||||||||||
Db         241 YSARHGLQWWEFDLTWLIICGLKKVGLARKIKVASPNN 278
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9. Applicants' arguments filed October 13, 2010 have been fully considered but they are not persuasive. Applicants argue that Nishizawa et al teach targeting the desaturase to plastids, but not to the ER, and that applicants have shown unexpected results in that the activity of the delta-9 desaturase can be increased by linking the enzyme to a KKXX sequence, as shown in Table 1 on page 25.

10. The Examiner maintains that the claims are broadly drawn to a nucleic acid encoding an Anacystis nidulans delta-9 desaturase in operable linkage with the amino acids KKXX. However, the amino acid sequence KKXX is found within the delta-9 desaturase coding sequence of Anacystis nidulans delta-9 desaturase of SEQ ID NO: 2 (see amino acids 63-66, KKVG) that is taught by Nishizawa et al, and the claims do not define "operable linkage" in a way that would exclude the presence of this amino acid sequence within the desaturase. Therefore, the claims are anticipated by Nishizawa et al, given that there are no limitations in the claim that distinguish the claimed nucleic acid sequence from that found in the prior art, and evidence of non-obviousness is not sufficient to overcome a rejection under 35 USC 102.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 11-17, 26 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishizawa et al (US Patent 6,043,411 in IDS) taken with Martin et al (WO 00/11012 A1 in IDS).

14. The claims are drawn to a nucleic acid molecule encoding a delta-9 desaturase coding sequence from a prokaryote operably linked to an endoplasmic reticulum (ER) retention and retrieval signal sequence, and said sequence in a vector, a host cell, a plant cell or transgenic plant, and a method comprising extracting oil from said plant.

15. Nishizawa et al teach a delta-9 desaturase coding sequence from the prokaryote Anacystis that encodes a polypeptide of SEQ ID NO: 2 (see sequence alignment below), wherein SEQ ID NO: 2 comprises the amino acid sequence of SEQ ID NO: 3 (KKXX at amino acids 63-66) and

transformation of plants and extraction of oils with reduced saturation of fatty acids (see the Brief Description at paragraphs 9-27, and the Detailed Description at paragraphs 47-58). In addition, Nishizawa et al teach that this prokaryotic gene is desirable to express in plants because it acts on 16:0 fatty acids that are abundant in plants (at paragraph 3 of the Brief Description), and that any known plant regulatory elements can be used in combination with said coding sequence for transformation of plant cells (see paragraph 15 of the Detailed Description).

16. Nishizawa et al do not specifically teach transformation of canola.

17. Martin et al teach transformation of plants with a nucleic acid molecule encoding a heterologous or synthetic delta-9 desaturase coding sequence operably linked to an endoplasmic reticulum (ER) retention and retrieval signal sequence, including the FAD2 sequence from Arabidopsis having a KKXX motif (page 61, line 18) and said sequence in a vector, a host cell, a plant cell or transgenic plant, including Brassica (mustard), olive (Olea), oil palm, and corn for producing plants with reduced levels of saturated fatty acids (see pages 1, 29-35 and 64, for example).

1. Given the recognition of those of ordinary skill in the art of the value of transforming a plant with a delta-9 desaturase sequence of SEQ ID NO: 2 that comprises a KKXX amino acid motif for the purpose of reducing saturated fatty acids in a plant, it would have been obvious of one of ordinary skill in the art to use the teachings of Nishizawa et al to transform other plant species, such as canola (Brassica) to produce plants having reduced levels of saturated fatty acids, as taught by Martin et al. Thus the claimed invention would have been prima facie obvious as a whole to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

18. Applicants' arguments filed October 13, 2010 have been fully considered but they are not persuasive. To the extent that applicants' arguments relate to the present rejection, applicants argue that Martin et al teach a 30 amino acid sequence, but not the 4 amino acid sequence of KKXX for use to target the delta-9 desaturase to the ER. In addition, applicants state that Martin et al do not provide any guidance for use of KKXX to target the delta-9 desaturase to the ER. Applicants further argue that Nishizawa et al teach targeting the desaturase to plastids, but not to the ER, and that applicants have shown unexpected results in that the activity of the delta-9 desaturase can be increased by linking the enzyme to a KKXX sequence, as shown in Table 1 on page 25.

19. The Examiner maintains that the claims are broadly drawn to a nucleic acid encoding an Anacystis nidulans delta-9 desaturase in operable linkage with the amino acids KKXX. However, the amino acid sequence KKXX is found within the delta-9 desaturase coding sequence of Anacystis nidulans delta-9 desaturase of SEQ ID NO: 2 (see amino acids 63-66, KKVG) that is taught by Nishizawa et al, and the claims do not define "operable linkage" in a way that would exclude the presence of this amino acid sequence within the desaturase. And while unexpected results are presented in Table 1, it is unclear what sequence was used to produce these results, and the claims are not limited to the particular sequence, having a KKXX sequence operably linked at a particular region of the desaturase polypeptide or a KKXX sequence other than KKSS. Thus the claimed invention appears obvious in view of the teachings of Nishizawa et al taken with Martin et al.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EFM

/Elizabeth F. McElwain/
Primary Examiner, Art Unit 1638